

MEDICAL DEVICE PACKAGING AND ANTISTATIC SYSTEM

RELATED APPLICATIONS

[0001] This application claims the benefit of and priority to U.S. Provisional Patent Application Ser. No. 60/653,205, filed Feb. 15, 2005, and entitled "MEDICAL DEVICE PACKAGING AND ANTISTATIC SYSTEM", the disclosure of which is incorporated herein by this reference.

BACKGROUND OF THE INVENTION

[0002] 1. The Field of the Invention

[0003] The present invention relates to devices and containers for holding and retaining medical devices. More particularly, the present invention relates to an improved medical device packaging system for use in storing and transporting one or more medical devices.

[0004] 2. The Relevant Technology

[0005] Many medical devices such as endoscopes, percutaneous transluminal coronary angioplasty ("PTCA") catheters, stent delivery catheters, balloon catheters, and the like are typically packaged within a protective sheath. For example, sheaths can protect a balloon located on the distal end of a catheter shaft as well as the shaft itself from accidental damage during storage, transit, and preparation for use. Normally, the sheath is coiled to enable the product to be packaged more efficiently in a container. Various types of retention devices have been used to retain the sheath and medical device in a coiled orientation. Additionally, various components that are operable with the medical device as well as instruction and label information are also enclosed in the container.

[0006] The proximal end of the catheter can include luer fitting, which projects clear of the sheath so that it is presented free for use by the physician. As such, the distal end of the catheter, which can include a delicate balloon, for example, can be retained safely within the coiled sheath. In addition, the sheath also retains the medical device in a sterile and clean environment. In part, this is because the medical device, sheath, and any other associated packaging (e.g., container) are typically sterilized together, wherein the sterile packaging remains sealed until use. However, the retention devices have been shown to puncture the containers and compromise sterility. Additionally, the various components and materials packaged with the medical device may compromise the integrity and sterility of the container.

[0007] Generally, the medical device is removed from the container and coiled sheath before being utilized in a medical procedure. The medical device can be rinsed with a sterile fluid such as saline solution in preparation for use. The wetted medical device is then typically placed on a sterile cloth covering a tray, or placed on a surgical drape where it remains until use. One shortcoming arises when the medical device is removed from the coiled sheath. As the medical device is being withdrawn from the sheath it has been found that a static charge builds on the device due to frictional interaction between the device and the lumen of the sheath. The formation of a static charge can cause small particles to be drawn and affix themselves to the medical device when it is placed onto the towel or drape. This is

problematic because any particulates adhering to the medical device can be introduced into the patient upon percutaneous transluminal insertion.

[0008] Accordingly, various techniques, such as washing with sterilized water, have been implemented in order to remove the particulates that adhere to the medical device. Animal studies have shown pressure rinsing of coronary stents immediately before implantation can reduce inflammation and neointimal hyperplasia. See, A. Baye-Gensi et al., *J AM Coll Cardiol*; 38: 562-8 (2001). Additionally, a stent may attract particulates from the materials (e.g., sterile covering cloth, gloves, and the like) used during the medical procedure. More particularly, particulates and fuzzes from these materials can adhere to the stent when it is withdrawn from the sheath and placed on the table before insertion into the patient.

[0009] Therefore, it would be advantageous to have a medical device packaging system that is improved to inhibit the sterility of the medical device from being compromised. Additionally, it would be beneficial to have improved packaging materials that reduce and/or eliminate the formation of a static electric charge when a medical device is removed from its protective packaging.

SUMMARY OF THE INVENTION

[0010] Generally, the present invention relates to packaging devices and systems for retaining medical devices. The packaging devices and systems can be configured to retain elongated medical devices such as catheters, endoscopes, and the like. Any of the various packaging devices and systems can be comprised of antistatic materials that inhibit and/or eliminate the formation of static electricity or static charge when the medical device is removed from the packaging devices or systems. The use of antistatic materials can thereby inhibit sterility from being compromised prior to use.

[0011] In one embodiment, the present invention can include a medical device sheath configured to hold and retain an elongate medical device disposed within a lumen of the sheath. The sheath can include an elongate tube having an outer surface and an inner surface defining the lumen, which is configured to releasably retain the elongate medical device. The elongate tube can be fabricated with a first material and an antistatic material. The antistatic material can be incorporated into the first material in an amount and distribution so as to inhibit the buildup of static electricity or charge. In part, the antistatic material inhibits static electricity or charge from being generated when the elongate medical device is withdrawn from the lumen.

[0012] In one embodiment, the present invention can include a clasp configured to hold and retain a medical device (e.g., catheter, endoscope, medical device sheath, etc.), during storage. The clasp can include a housing having an outer end and an inner end. The housing can include at least two recesses formed therein, and each recess can be configured for releasably retaining an elongate tube such as a sheath. Accordingly, the at least two recesses can hold the elongate tube in at least a double coil orientation so that a coil passes through each one of the recesses. As such, the recesses can be substantially parallel with respect to each other.